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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,694

03/24/2008

Andrew S. Goldsborough

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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,694	Applicant(s) GOLDSBOROUGH, ANDREW S.	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-60 is/are pending in the application.
- 4a) Of the above claim(s) 59 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/24/08; 1/23/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 40-58, in the reply filed on December 18, 2008 is acknowledged. Thus, the restriction requirement is still deemed proper and hereby made FINAL. As such, claim(s) 59 and 60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following rejection(s) are made in view of Applicant's amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The above claim is indefinite because it is unclear whether the claimed invention is directed to a method or an apparatus. In other words, it is unclear how the recited method steps limit the claimed product. In the instant case, the claimed "set of

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materials" recites the steps "wherein the solid phase binds" (claims 40, (b)) and "binds the solid phase" (claim 41).

In support of the examiner's position, Applicant is directed to a recent Federal Circuit decision, *IPXL Holdings, LLC v. Amazon.com, Inc.*, 333 F. Supp. 2d 513 (E.D. Va. 2004), which the Federal Circuit affirmed in part, 2005 U.S. App. LEXIS 25120, where after upholding the district court's claim constructions and affirming the finding that all but one of the asserted claims were anticipated, the Federal Circuit next affirmed the summary judgment of invalidity (for indefiniteness) for the remaining asserted claim, which read:

25. The system of claim 2 [including an input means] wherein the predicted transaction information comprises both a transaction type and transaction parameters associated with that transaction type, and the user uses the input means to either change the predicted transaction information or accept the displayed transaction type and transaction parameters.

Claim 25 on its face is directed to a "system." However, it also recites use steps ("the user uses the input means to ...change the predicted transaction information ... ") This claim was found indefinite by the district court. Applicant is notified that proper incorporation of a phrase such as "is capable of binding" in place of the aforementioned phrases would obviate the instant rejection.

(b) Claim 58 recites the limitation "the underlying surface phase" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-45, 47-54, 57, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Mirkin et al. (WO 01/73123 A2; 28 March 2001).

As an initial matter, Applicant is notified that the terms "analyte" and "undesired" are not limiting as they are related to the intended use of the solid phase. Furthermore, the term "impeded" does not necessarily incorporate a degree of impedance.

Mirkin discloses a set of materials (fig. 56; pg. 187-188 example 26, for example) comprising: a) the first composition of matter is a sample (*pg. 187-188, example 26, mixture reacting biotinylated oligonucleotide (SEQ ID NO: 73) with streptavidin in the presence of EDTA, for example*) comprising an analyte and an undesired constituent, wherein the analyte is a polynucleotide (*pg. 187-188, example 26, biotinylated oligonucleotide (SEQ ID NO: 73), for example*), and the undesired constituent is a chelator (*pg. 187-188, example 26, EDTA, for example*); and b) the second composition of matter is a material comprising a composition comprising a solid phase that is coated with polynucleotides at least 20 nucleotides in length (*pg. 187-188, example 26, Au nanoparticle-oligonucleotide (SEQ ID NO: 74) conjugate; pg. 54, also teaches magnetic metal nanoparticles, for example*), wherein the solid phase binds the undesired

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constituent (*the Au particle naturally attracts and binds the EDTA*) and the polynucleotide coating covers the exposed surface of the solid phase to an extent that any binding of the solid phase to the analyte is impeded (*steric hindrance provided by the oligonucleotide conjugated to the nanoparticle naturally impedes the binding of the biotinylated oligonucleotide*), wherein the sample and the second material are not in contact with each other (*such reactants are separate from each other*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (WO 01/73123 A2; 28 March 2001) in view of Wakamura et al. (JP 2000-327315; 28 November 2000; translation provided by JPO).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach magnetic hydroxyapatite.

Wakamura teaches the production of magnetic hydroxyapatite particles (see translation @ [0011], teaches iron oxide hydroxyapatite; [0017], in the form of particles, for example).

Thus, in summary, absent a secondary consideration, it is submitted that it would have been *prima facie* obvious to a skilled artisan at the time of invention to produce a magnetic hydroxyapatite nanoparticle within the reactants of Mirkin since the prior art demonstrates such a material as suitable for such a use.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Patent Examiner
Art Unit 1637
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